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May 19, 2004

Michael O. Leavitt, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for the aromatic extracts category

Dear Administrator Leavitt:

The following comments on the American Petroleum Institute's Petroleum HPV Testing Program (API) test plan for the aromatic extracts category are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

API submitted its test plan on December 15, 2003, for the aromatic extracts category (AEC), which can be categorized into two subcategories, distillate aromatic extracts (DAE) and residuum aromatic extracts (RAE). The major uses and hazards for this chemical are well characterized in the test plan, and a concise and complete description is given for the required endpoints. The OECD SIDS data endpoints required by the program are fulfilled using existing data, and no new testing is proposed. Repeat-dose, ecotoxicity, developmental toxicity, and genetic toxicity endpoints are satisfied through existing data from studies conducted according to OECD guidelines. Acute toxicity, biodegradation, and toxicity to algae endpoints are fulfilled by reading across the category, a strategy consistent with the aim of minimizing testing. API uses a rational toxicology approach, taking into account physicochemical data in order to fill gaps in knowledge of the two chemical subcategories.

The reproductive toxicity endpoint is satisfied for both DAE and RAE by using data from repeat-dose studies where reproductive organs were examined histologically, plus a valid developmental toxicity study for both. By proposing to fulfill this endpoint using this strategy, the API is conforming to both OECD and EPA guidance, and following the lead of several other sponsors.

The EPA has clearly stated that an "evaluation of reproduction organs from . . . repeated-dose toxicity studies adequately address this [reproductive] endpoint." The OECD states

in its Manual for Investigation of HPV Chemicals that when repeated dose studies that include the effects of reproductive organs and a developmental study are available, "the requirements for the reproduction toxicity endpoint would be satisfied" (Chapter 4).

In this particular case, the API has conducted a thoughtful analysis of the data and summarized this analysis in a clear and concise manner. This approach is consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to toxicology.

Thank you for your attention to these comments. We may be reached at 202-686-2210, ext. 335, or via email at kstoick@pcrm.org.

Sincerely,

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